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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,704	12/30/1999	SUSAN W. BARNETT	1631.002	6738

27476 7590 12/15/2006

NOVARTIS VACCINES AND DIAGNOSTICS INC.
CORPORATE INTELLECTUAL PROPERTY R338
P.O. BOX 8097
Emeryville, CA 94662-8097

EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/475,704	Applicant(s) BARNETT ET AL.	
	Examiner Brian Whiteman	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *20 November 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *69,71 and 73*.
   Claim(s) objected to: *6 and 75*.
   Claim(s) rejected: *2,4,5,7-10,24-43,49-60,63-66,70,72 and 74*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: In view of the lengthy prosecution, the majority of applicant's arguments have already been addressed in previous office actions. The invention is directed to an expression cassette comprising a polynucleotide encoding an HIV Gag polypeptide that is immunogenic and where the polynucleotide is 90% identical to SEQ ID NO: 3 or 4 and using the cassette in a method to produce an immune response in a mammal. The Gag sequences are different than Gag sequences found in nature because the coding sequences were modified to be comparable to codon usage found in highly expressed human genes (page 67). A search of the sequences in the public databases indicates that there are no known sequences with at least 90% to SEQ IDNO: 3 or 4. The working examples are prophetic examples. The applicant asserts that the expression cassettes will provide a clear improvement of immunogenicity relative to the native expression cassettes (page 76).

In response to applicant's argument that the claims are only directed to nucleotide sequence encompasses only those nucleotide sequences that encode a polypeptide that elicits a humoral and/or cellular immune response specific for an HIV Gag polypeptide, the argument is not found persuasive because while it is acknowledged that the claimed product embraces an immunogenic Gag polypeptide, the claimed product also embrace a functional Gag polypeptide. There is nothing in the claim that excludes an HIV Gag polypeptide, wherein the polypeptide does possess an activity of a functional Gag protein. As stated above, the applicant modify the nucleotide sequence encoding an HIV Gag polypeptide and assert that the polypeptide will provide a clear improvement of immunogenicity relative to the native HIV gag polypeptide without any evidence of record to support the assertion. The description of an immunogenic composition in the specification is a general definition of the term and does not distinguish between a polypeptide found in the prior art and the claimed invention (improvement of immunogenicity relative to a native HIV Gag protein).

In response to applicant's argument that written description does not require description of the sequence of known molecules and that literature available at the time of filing must be considered in determining the adequacy fo the written description (Falkner v. Inglis, 79 USPQ2d 1001 (Fed. Cirl 2006), the argument is not found persuasive because the sequences are not known molecules in the prior art as indicated by a sequence search of public databases against SEQ ID NO:3 and 4. There are no known sequences that are at least 90% identical to SEQ ID NO: 3 or 4 and have the desired biological activity. There is nothing of record to indicate that modifying a Gag sequence with codons used in highly expressed human genes was known to the skilled artisan.

In response to applicant's argument that the Delcaration of Dr. Ulmer supports that the instant specification provides written description for the claimed product, the argument is not found persuasive for the reasons of record. See office action mailed on 7/30/04.

In response to applicant's argument that possession of a genus is not determined by the amount of testing required and the specification provides written description for every member of the claimed genus be it 2 or 2 billion, the argument is not found persuasive because the skilled artisan would be required to further experiment to determine if a polynucleotide having 90% identity to SEQ ID NO: 3 or 4 has the desired biological activity. On page 76 applicant asserts that the expression cassettes will provide a clear improvement of immunogenicity relative to native expression cassetes, but does not provide any factual evidence to support the assertion. The art of record is absent for determining whether modiyfing a Gag polypeptide with codons found in highly expressed human genes results in improved immunogenicity.

In response to applicant's argument that reduction to practice is not required to satisfy the written description, the argument is not found persuasive because while it is acknowledged that the reduction to practice is not required to satisfy written description, the specification should provide sufficient guidance for how to make the claimed genus and disclose a correlation between the structure of the polynucleotides and desired biological activity (See Written Description Examination guidelines were published on January 5, 2001 (66 FR 1099) and are available at http://www.uspto.gov/web/menu/current.html#register.). In view of the specification not providing sufficient guidance to support the claimed genus of polynucleotides for the reasons set forth in prior office actions, one skilled in the art would recognize from the disclosure that applicant was not in possession of the claimed genus of polynucleotides.

In response to applicant's argument against the references cited in the enablement do not support the enablement rejection, the argument is not found persuasive for the reasons of record. See office action mailed on 7/30/04

In response to applicant's argument that the the only function required by the polypeptide is that it elicits a Gag-specific immune response and which required function does not necessiate the entire coding sequence or core structures, the argument is not found persuasive because there is nothing in the claims that excludes an HIV Gag polypeptide having a Gag activity of a functional Gag protein, including immunogenicity. The desription of an immunogenic composition in the specification is a general description of any polypeptide and the specification does not teach how to make and use the claimed invention wherein the polynucleotide has a clear improvement of immunogenicity relative to a native HIV Gag polypeptide.

In response to applicant's argument that it is not undue experimentation to make and use the genus of polynucleoides since it is routine to make the claimed genus, the argument is not found persuasive for the reasons of record. See office action mailed on 7/30/04. In addition, there is no evidence of record to support the assertion that it was routine to make and use a polynucleotide having codons found in highly expressed human genes, wherein the polynucleotide has a clear improvement of immunogenicity relaive to the native expression cassettes.

In response to applicant's argument that Ref FX-1 WO 00/39302 of IDS filed on 12/18/02 now US Patent 6,602,705 demonstrates that synthetic polynucleotides similar to those claimed encode immunogenic Gag polypeptides, the argument is not found persuasive for the reasons of record. See office action mailed on 11/16/05.

In response to applicant's argument reasserting that the Delcarations of record indicate that the specifiction provides enablement for the claimed invention, the argument is not found persuasive for the reasons of record. See office actions mailed on 7/30/04 and 11/17/03.

Applicant's argument against the provisional ODP have already been addressed in a previous office action and the rejections remain for the reasons of record. See office action mailed on 8/7/06..